UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

MARY A. MARTELLARO,	)	
	)	
Plaintiffs,	)	**CASE NO. 21-637**
VS.	)	
	)	**JURY TRIAL DEMANDED**
COOK INCORPORATED, COOK MEDICAL LLC f/k/a COOK MEDICAL INCORPORATED, and WILLIAM COOK EUROPE APS	)	
	)	
Defendant.	)	

COMPLAINT

COMES NOW, MARY A. MARTELLARO (hereinafter "Plaintiff"), by and through her undersigned counsel, O'Leary, Shelton, Corrigan, Peterson, Dalton & Quillin, LLC, files this Complaint against Defendants COOK INCORPORATED, COOK MEDICAL LLC f/k/a COOK MEDICAL INCORPORATED, and WILLIAM COOK EUROPE APS (hereinafter "Defendants"), state to the Court as follows:

I. INTRODUCTION

1. This is an action for damages relating to Defendants' development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling defective product sold under the name "inferior vena cava filter" (hereinafter "IVC filter").

2. Cook IVC Filters are associated with, and cause, an increased risk for serious injury and death as a result of adverse events including: tilting, perforation, fracture, breakage and migration.

3. At all times relevant to this action, Cook intentionally, recklessly, and/or negligently failed to act as to the known failures and injuries associated with its devices and/or failed to warn about and concealed, suppressed, omitted, and/or misrepresented the risks, dangers, defects and disadvantages of its IVC filters.

4. At all times relevant to this action, Cook intentionally, recklessly, and/or negligently advertised, labeled, promoted, marketed, sold and/or distributed its IVC Filters as a safe medical device when in fact Cook had reason to know, and/or did know, that its IVC Filters were not safe for its intended purposes, and that its IVC Filters caused serious injury and death.

5. At all times relevant to this action, Cook is and was strictly liable for injuries caused by its IVC Filters because the devices are unreasonably dangerous and not accompanied by adequate warnings about its danger.

II. THE PARTIES

6. Plaintiff Mary A. Martellaro at all times relevant to this action was a citizen and resident of the State of Missouri.

7. Defendant Cook Incorporated is an Indiana Corporation with its principal place of business located at 750 Daniels Way, P.O. Box 489, Bloomington, Indiana. Defendant Cook Incorporated is authorized and/or doing business in the State of Missouri, including Saint Louis County. At all times relevant to this action, Cook Incorporated designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed and/or sold its inferior vena cava filters ("IVC Filters") to be implanted in patients throughout the United States, including Missouri. At all times relevant hereto, Defendant Cook Incorporated was engaged in business in Missouri, has conducted substantial business activities

and derived substantial revenue from within the State of Missouri. Defendant has also carried on solicitations or service activities in Missouri. The registered agent for Cook Incorporated is Corporation Service Company, 135 North Pennsylvania Street, Suite 1610, Indianapolis, IN 46204. Cook Incorporated may be served with process by delivering a Summons with a copy of this Complaint attached thereto, to its registered agent.

8. On information and belief, Cook Incorporated is a privately-owned corporation with wholly owned subsidiaries that it controlled, including Cook Medical, LLC f/k/a Cook Medical Incorporated, and William Cook Europe APS.

9. Defendant Cook Medical, LLC is a privately-owned Indiana limited liability company with its principal place of business located at 1025 West Acuff Road, Bloomington, Indiana 47404. Cook Medical, LLC was formerly known as Cook Medical Incorporated. Cook Medical, LLC is doing business in the state of Missouri, including Saint Louis County. At all times relevant to this action, Cook Medical, LLC designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed and/or sold its IVC Filters to be implanted in patients throughout the United States, including Missouri. At all times relevant hereto, Defendant Cook Medical, LLC was engaged in business in Missouri has conducted substantial business activities and derived substantial revenue from within the State of Missouri. This Defendant has also carried on solicitations or service activities in Missouri. The registered agent for Cook Medical, LLC is Corporation Service Company, 135 North Pennsylvania Street, Suite 1610, Indianapolis, IN 46204. Cook Medical, LLC may be served with process by delivering a Summons with a copy of this Complaint attached thereto, to its registered agent.

10. Defendants Cook Incorporated, Cook Medical LLC f/k/a Cook Medical

Incorporated, and Cook Group Incorporated are hereinafter collectively referred to as "Cook Defendants" or "Cook."

11. Defendant William Cook Europe APS (hereinafter "Cook Europe") is a foreign corporation with its principal place of business located at Sandet 6, Bjaverskov 4632, Denmark, and is authorized to do business in the state of Missouri. Cook Europe's business form most closely resembles that of an American Corporation. Cook Europe's headquarters is based at Sandet 6, Bjaverskov 4632, Denmark. Cook Europe is incorporated in and under the laws of Denmark. Cook Europe was not incorporated in the state of Missouri, nor does it have its principal place of business in the state of Missouri. Because Cook Europe is incorporated under the laws of Denmark and has its principal place of business in Denmark, diversity of citizenship exits between Plaintiff and Cook Europe. Cook Europe conducted research and contributed to the development, the design, testing and manufacture, as well as marketing and distribution of the inferior vena cava filter implanted in Plaintiff. Cook Europe conducted regular and sustained business by selling and distributing its products in Missouri. Defendant also carried on solicitations or service activities in the state of Missouri.

12. At all relevant times, the Cook Defendants were in the business of designing, setting specifications for, manufacturing, preparing, compounding, assembling, processing, marketing, packaging, and selling its IVC filters to distributors and sellers, including hospitals, for implantation by physicians at hospitals in patients throughout the United States, including in Missouri.

13. At all relevant times, each of the Cook Defendants regularly marketed, distributed and sold its IVC filters throughout Missouri and sold its IVC filters in Missouri for resale and implantation into human patients, including Plaintiff.

14. At all relevant times, each of the Cook Defendants and their directors and officers acted within the scope of their authority. At all relevant times each Cook defendant was responsible for each other's actions and inactions; and each Cook defendant acted on behalf of each other Cook defendant.

15. At all relevant times, the Cook Defendants possessed a unity of interest between themselves and Cook. Cook exercised control over its subsidiaries and affiliates. As such, each Cook Defendant is responsible jointly and severally to Plaintiff for her injuries, losses and damages.

IV. JURISDICTION AND VENUE

16. The Court has subject matter jurisdiction over this matter because there is complete diversity as the parties are citizens of different states and the amount in controversy exceeds $75,000, exclusive of interest and costs. See 28 U.S.C. § 1332.

17. The Court has personal jurisdiction over the Cook Defendants because they have sufficient minimum contacts such that asserting jurisdiction over the defendants does not offend traditional notions of fair play and substantial justice. *International Shoe v. Washington*, 326 U.S. 310, 325 (1945). The Cook Defendants have conducted and continue to conduct substantial and systematic business activities related to their IVC filters, in this jurisdiction. Such activities include, but are not limited to: (a) sales of IVC filters, including the Cook filter at issue in this case, in this jurisdiction; (b) hiring, training, and deploying employees, including managers and sales representatives, in this jurisdiction; (c) advertising and marketing of their IVC filters, including the Cook filter at issue in this case, in this jurisdiction; (d) maintenance of company files and equipment relating to the Cook filter in this case, in this jurisdiction; (e) payment of employee salaries in this jurisdiction; and (f) maintenance of a website directed to all states,

including Missouri. The Cook Defendants also committed tortious acts within the State of Missouri and caused injury to persons or property within the State of Missouri arising out of acts or omissions by the Cook Defendant outside this state at or about the time of the Plaintiff's injury, while the Cook Defendants were engaged in solicitation or service activities within the State of Missouri; and/or, while products, materials, or things processed, serviced, or manufactured by the Cook Defendants were used or consumed within Missouri in the ordinary course of commerce, trade, or use.

18. Plaintiffs have filed this lawsuit in a timely fashion, from the time the Plaintiffs knew or reasonably knew of the injury and that it may have been wrongfully caused.

19. Venue is proper in this district because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this district. See 28 U.S.C. § 1391(b)(2). The Cook Defendants' Cook filter was marketed, sold, and implanted in the state of Missouri.

V. FACTS

COOK INFERIOR VENA CAVA FILTERS GENERALLY

20. Defendants design, research, develop, manufacturer, test, market, advertise, promote, distribute, and sell products that are sold to and marketed to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. Defendants' products include the Cook Celect Vena Cava Filter and the Gunther Tulip Filter (collectively referred to herein as "Cook Filters"), which are introduced via a coaxial introducer sheath system.

21. Defendants sought Food and Drug Administration ("FDA") approval to market the Cook Filters and/or its components under Section 510(k) of the Medical Device Amendment.

22. Section 510(k) allows marketing of medical devices if the device is substantially

equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" process in an amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp*., 376 F.3d 163, 167 (3d Cir. 2004):

> A manufacturer can obtain an FDA finding of "substantial equivalence" by submitting a premarket notification to the agency in accordance with section 510(k)…A device found to be 'substantially equivalent' to a predicate device is said to be "cleared" by FDA (as opposed to "approved" by the agency under a [premarket approval]). A pre-market notification submitted under 510(k) is thus entirely different from a [pre-market approval] which must include data sufficient to demonstrate that the device is safe and effective. (Emphasis in original).

23. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470,478-79 (1996), the Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] §510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…The §510(k) notification process is by no means comparable to the [premarket approval] process; in contract to the 1,200 hours necessary to complete a PMA review, the §510(k) review is completed in average of 20 hours…Section §510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets process quickly.

24. An IVC filter, like the Cook Filters, is a device designed to filter blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC

filters may be designed to be implanted, either temporarily or permanently, within the vena cava.

25. The inferior vena cava is a vein that returns blood to the heart from the lower portion of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. Often these thrombi develop in the deep leg veins. The thrombi are called "deep vein thrombosis" or DVT. Once the thrombi reach the lungs they are considered "pulmonary emboli" or PE. An IVC filter, like the Cook IVC Filters, is designed to prevent thromboembolic events.

26. The Cook Filters are retrievable filters.

27. The Cook Celect® Vena Cava Filter has four (4) anchoring struts for fixation and eight (8) independent secondary struts to improve self-centering and clot trapping.

28. The Gunther Tulip® Vena Cava Filter has a top hook and (4) anchoring struts for fixation and on each strut, it has a "flower" formation that is shorter than the strut where a wire piece branches out on each side of the strut forming an overall "flower" type formation on each strut.

29. At all times relevant hereto, the Cook Filters were widely advertised and promoted by the Defendants as safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava. At all times relevant hereto, Defendants knew its Cook Filters were defective and knew that defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.

30. A retrospective review of all Cook Gunther Tulip Filters and Cook Celect filters retrieved between July 2006 and February 2008 was performed. One hundred and thirty (130) filter retrievals were attempted but in 33 cases, the standard retrieval technique failed. The

authors concluded that "unsuccessful retrieval was due to significant endothelialization and caval penetration" and that "hook endothelialization is the main factor resulting in failed retrieval and continues to be a limitation with these filters." O. Doody, et al.; "Assessment of Snared-Loop Technique When Standard Retrieval of Inferior Vena Cava Filters Fail" Cardiovasc Intervent Radiol (Sept 4, 2008 Technical Note).

31. A retrospective review of 115 patients who underwent Cook Celect IVC filter insertion between December 2005 and October 2007 was performed. While filter insertion was successful in all patients, the authors also concluded that "[f]ailed retrieval secondary to hook endothelialization continues to be an issue with this filter." O. Doody, et al; Journal of Medical Imaging and Radiation Oncology "Initial Experience in 115 patients with the retrievable Cook Celect vena cava filter" 53 (2009) 64-68 (original article).

32. In a review of clinical data related to 73 patients who had Celect IVC filter implanted between August 2007 and June 2008, the authors found that the Celect IVC filter was related to a high incidence of caval filter leg penetration. Immediately after fluoroscopy-guided filter deployment in 61 patients, four filters (6.5%) showed significant tilt. Follow-up abdominal CT in 18 patients demonstrated filter related problems in 7 (39%), which included penetration of filter legs in 4 and fracture/migration of filter components in 1.

33. In a study of Gunther Tulip and Celect IVC filters implanted between July 2007 and May of 2009 reported by Cardiovascular Interventional Radiology electronically on March 30, 2011 and published by journal in April 2012, one hundred percent of the Cook Celect filters and Gunther Tulip filters imaged after 71 days of implant caused some degree of filter perforation of the venal caval wall. Durack JC, et al, Cardiovasc Intervent Radiol., "Perforation of the IVC: rule rather than the exception after longer indwelling times for the Gunther Tulip

and Celect Retrievable Filters," 2012 Apr.; 35(2):299-308. Epub 2011 Mar 30. The authors concluded: "Although infrequently reported in the clinical literature, clinical sequelae from IVC filter components breaching the vena cava can be significant." Defendants knew or should have known that their IVC filters were more likely than not to perforate the vena cava wall.

34. This same study reported that tilt was seen in 20 out of 50 (40%) of the implanted Gunther Tulip and Celect IVC filters and all tilted filters also demonstrated vena caval perforation. Defendants knew or should have known that their IVC filters were more likely than not to tilt and to perforate.

35. While not inclusive of all medical studies published during the relevant time period, the above references show that the Defendants failed to disclose to physicians, patients and/or Plaintiff that its Cook Filters were subject to breakage, tilt, inability of removal, and migration even though they knew or should have known the same was true.

36. At all times relevant hereto, the Defendants continued to promote the Cook Filter as safe and effective even when inadequate clinical trials had been performed to support long or short to safety and/or efficacy.

37. The Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Cook Filters, as aforesaid.

38. The Cook Filters are constructed of conichrome.

39. The Defendants specifically advertise the conichrome construction of the filter as a frame which "reduces the risk of fracture."

40. The failure of the Cook Filters is attributable, in part, to the fact that the Cook Filters suffer from a design defect causing it to be unable to withstand the normal anatomical and physiological loading cycles exerted in vivo.

41. At all times relevant hereto, the Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Cook Filters, including, but not limited to the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.

42. The Cook Filters were designed, manufactured, distributed, sold and/or supplied by the Defendants, and were marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Defendants' knowledge of the products' failure and serious adverse events.

43. That at all times relevant hereto, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of the said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

Plaintiff's Cook Filter and Injuries

44. Plaintiff Mary A. Martellaro was implanted with a Cook Gunther Tulip Inferior Vena Cava (IVC) Filter at Saint Anthony's Medical Center in Missouri.

45. On or about June 6, 2017, an attempt was made at retrieving the filter; however, the filter was tilted and deeply embedded in the IVC wall and was unable to be retrieved.

46. Plaintiff has also suffered significant injuries, including significant pain and distress.

47. Furthermore, Plaintiff has incurred substantial medical expenses as a result of Cook's defective device.

COUNT I
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

48. Plaintiff repeats and realleges all previous paragraphs.

49. Cook Filters were defective and unreasonably dangerous when they left the possession of the Defendants in that they contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

50. Information provided by Cook to the medical community and to consumers concerning the safety and efficacy of its Cook Filters did not accurately reflect the serious and potentially fatal adverse events Plaintiff could suffer.

51. At all times relevant hereto, the Cook Filters were dangerous and presented a substantial danger to patients who were implanted with the Cook Filter, and these risks and dangers were known or knowable at the times of distribution and implantation in Plaintiff. Ordinary consumers would not have recognized the potential risks and dangers the Cook Filters posed to patients, because their use was specifically promoted to improve health of such patients.

52. Had adequate warnings and instructions been provided, Plaintiff would not have been implanted with the Cook filter and would not have been at risk of the harmful injuries described herein. The Cook Defendants failed to provide warnings of such risks and dangers to Plaintiff and their medical providers as described herein. Neither Plaintiff, nor Plaintiff's physicians knew, nor could they have learned through the exercise of reasonable care, the risks of serious injury and/or death associated with and/or caused by Cooks' Filters.

53. Cook Defendants knew or had knowledge that the warnings that were given failed to properly warn of the increased risks of serious injury and/or death associated with and/or caused by Cook Filters.

54. Plaintiff, individually and through her implanting physician, reasonably relied upon the skill, superior knowledge, and judgment of the Cook Defendants.

55. Cook Defendants were under a continuing duty to warn Plaintiff and her physicians of the dangers associated with the filter.

56. Safer alternatives were available that were effective and without risks posed by Cook's Filters.

57. As a direct and proximate result of the Cook Filter's defects, as described herein, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost her ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has medical bills, both past and future, related to care because of the Cook Filters' defects.

58. By reason of the foregoing, Cook Defendants are liable to Plaintiff for damages as a result of their failure to warn and/or adequately warn the Plaintiff and her healthcare professionals about the increased risk of serious injury and death caused by their defective Cook filters.

59. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and other such other and further relief as this Court deems just and proper.

COUNT II
STRICT LIABILITY – DESIGN DEFECT

60. Plaintiff repeats and realleges all previous paragraphs.

61. Cook Defendants have a duty to provide adequate warnings and instructions for their products including their Cook Filters, to use reasonable care to design a product that is not unreasonably dangerous to users.

62. At all times relevant to this action, Cook Defendants designed, tested, manufactured, packaged, labeled, marketed, distributed, promoted and sold their Cook Filters, placing the devices into the stream of commerce.

63. At all times relevant to this action, Cook's Filters were designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Cook Defendants in a condition that was defective and unreasonably dangerous to consumers, including Plaintiff.

64. Cook Filters are defective in their design and/or formulation in that they are not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with their design and formulation.

65. Cook Filters were expected to reach, and did reach, users and/or consumers including Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which they were manufactured and sold.

66. Physicians implanted as instructed via the Instructions for Use and in a foreseeable manner as normally intended, recommended, promoted, and marketed by the Cook Defendants. Plaintiff received and utilized Cook Filters in a foreseeable manner as normally intended recommend, promoted, and marketed by the Cook Defendants.

67. Cook Filters were and are unreasonably dangerous in that, as designed, failed to perform safely when used by ordinary consumers, including Plaintiff, including when the filters were used as intended and in a reasonably foreseeable manner.

68. Cook Filters were and are unreasonably dangerous and defective in design or formulation for their intended use in that, when they left the hands of the manufacturers and/or supplier, they posed a risk of serious vascular and other serious injury which could have been reduced or avoided, inter alia, by the adoption of a feasible reasonable alternative design. There were safer alternative designs for the like products.

69. Cook Filters were insufficiently tested and caused harmful adverse events that outweighed any potential utility.

70. Cook Filters, as manufactured and supplied, were defective due to inadequate warnings, and/or inadequate clinical trials, testing, and study, and inadequate reporting regarding the results of the clinical trials, testing and study.

71. Cook Filters, as manufactured and supplied, were defective due to its no longer being substantially equivalent to its predicate device with regard to safety and effectiveness.

72. Cook Filters as manufactured and supplied by the Cook Defendants are and were defective due to inadequate post-marketing warnings or instructions because, after Cook Defendants knew or should have known of the risk of injuries from use and acquired additional knowledge and information confirming the defective and dangerous nature of its Cook Filters, Cook Defendants failed to provide adequate warnings to the medical community and the consumers, to whom Cook Defendants were directly marketing and advertising; and further, Cook Defendants continued to affirmatively promote their Cook Filters as safe and effective and as safe and effective as their predicate device.

73. As a direct and proximate result of the Cook Filter's defects, as described herein, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost her ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has medical bills, both past and future, related to care because of the Cook Filters' defects.

74. By reason of the foregoing, Cook Defendants are liable to Plaintiff for damages as a result of their failure to warn and/or adequately warn the Plaintiff and her healthcare professionals about the increased risk of serious injury and death caused by their defective Cook filters.

75. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and other such other and further relief as this Court deems just and proper.

COUNT III
NEGLIGENCE

76. Plaintiff incorporates by reference each and every allegation set forth in the preceding paragraphs as if fully stated herein.

77. At all times relevant to this cause of action, the Cook Defendants were in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including its Cook Filters.

78. At all times relevant hereto, the Cook Defendants were under a duty to act reasonably to design, develop, manufacture, market and sell a product that did not present a risk

of harm or injury to the Plaintiff and to those people receiving their Filters.

79. At the time of manufacture and sale of the Cook Filters, the Cook Defendants knew or reasonably should have known the Cook Filters:

a. were designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device, as aforesaid;

b. were designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device, as aforesaid;

c. were designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and/or

d. were designed and manufactured so as to present an unreasonable risk of perforation and damage to the vena caval wall

80. Despite the aforementioned duty on the part of the Cook Defendants, they committed one or more breaches of their duty of reasonable care and were negligent in:

a. unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Cook Filters, specifically its incidents fracture, migration, perforation and other failure;

b. unreasonably and carelessly manufacturing a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;

c. unreasonably and carelessly designed a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body; and

d. unreasonably and carelessly designed a product that presented a risk of harm to the Plaintiff and others similarly situated in that it was prone to fail.

81. As a direct and proximate result of the Cook Filter's defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into

the future. Plaintiff has lost her ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has medical bills both past and future related to care because of the Cook Filter's defects.

82. By reason of the foregoing, Cook Defendants are liable to the Plaintiff for damages as a result of their failure to warn and/or adequately warn the Plaintiff and her healthcare professionals about the increased risk of serious injury and death caused by their defective Cook filters.

83. WHEREFORE, Plaintiff, demands judgment against the Cook Defendants and seeks damages, including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other an further relief as this Court deems just and proper.

COUNT IV
NEGLIGENCE PER SE
(Violation of 21 U.S.C. §§321, 331, 352 and 21 C.F.R. §§1.21, 801, 803, 807, 820)

84. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

85. At all times herein mentioned, Defendants had an obligation not to violate the law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the manufacture, design, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, promotion, labeling, packaging, preparation for use, consulting, sale, warning and post-sale warning and other communications of the risks and dangers of Cook IVC Filters.

86. By reason of its conduct as alleged herein, Cook violated provisions of statutes and regulations, including but not limited to, the following:

a. Cook violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 352, by misbranding its Cook IVC Filters;

b. Cook violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321 in making statements and/or representations via word, design, device or any combination thereof failing to reveal material facts with respect to the consequences that may result from the use of Cook IVC Filters to which the labeling and advertising relates;

c. Cook violated 21 C.F.R. §1.21 in misleading the consumers and patients by concealing material facts in light of representations made regarding safety and efficacy of its Cook IVC Filters;

d. Cook violated 21 C.F.R. §801 in mislabeling its Cook IVC Filters as to safety and effectiveness of its products and by failing to update its label to reflect post-marketing evidence that Cook IVC Filters were associated with an increased risk of injuries due to tilting, fracture, migration and perforation;

e. Cook violated 21 C.F.R. §803 by not maintaining accurate medical device reports regarding adverse events of tilting, fracture, migration, perforation and complex removal procedures and/or misreporting these adverse events maintained via the medical device reporting system;

f. Cook violated 21 C.F.R. §807 by failing to notify the FDA and/or the consuming public when its Cook IVC Filters were no longer substantially equivalent with regard to safety and efficacy with regard to post-marketing adverse events and safety signals; and

g. Cook violated 21 C.F.R. §820 by failing to maintain adequate quality systems regulation including, but not limited to, instituting effective corrective and preventative actions,

87. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and other such other and further relief as this Court deems just and proper.

COUNT V
BREACH OF EXPRESS WARRANTY

88. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in

full herein.

89. At all times relevant to this cause of action, the Cook Defendants were merchants of goods of the kind including medical devices and vena cava filters (i.e., Cook Filters).

90. At the time and place of sale, distribution, and supply of the Cook Filter to Plaintiff (and to other consumers and the medical community), Cook expressly represented and warranted in their marketing materials, both written and orally, and in the IFUs, that the Cook Filters were safe, well-tolerated, efficacious, and fit for their intended purpose and were of marketable quality, that they did not produce any unwarned-of dangerous side effects, and that they were adequately tested.

91. At the time of Plaintiff's purchase from the Cook Defendants, the Cook Filters was not in a merchantable condition and the Cook Defendants breached their expressed warranties, in that the filter:

a. was designed in such a manner so as to be prone to an unreasonably high incident of fracture, perforation of vessels and organs, and/or migration;

b. was designed in such a manner so as to result in an unreasonably high incident of injury to the organs of its purchaser; and

c. was manufactured in such a manner so that the exterior surface of the Cook Filter was inadequately, improperly and inappropriately designed causing the device to weaken and fail.

92. As a direct and proximate result of the Cook Filter's defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability, and impairment. Plaintiff suffered emotional trauma, harm, and injuries that will continue into the future. Plaintiff has lost her ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into

the future and have medical bills both past and future related to care because of the Cook Filter's defect.

93. By reason of the foregoing, the Cook Defendants are liable to Plaintiff for damages as a result of their breach express warranty.

94. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and other such other and further relief as this Court deems just and proper.

COUNT VI
BREACH OF IMPLIED WARRANTY

95. Plaintiffs repeat and reiterate the allegations previously set forth herein.

96. At all relevant and material times, the Cook Defendants manufactured, distributed, advertised, promoted, and sold its Cook Filters.

97. At all relevant times, the Cook Defendants intended its Cook Filters be used in the manner that Plaintiff in fact used them.

98. Cook impliedly warranted their Cook Filters to be of merchantable quality, safe and fit for the use for which the Cook Defendants intended them and for which Plaintiff in fact used them.

99. The Cook Defendants breached their implied warranties as follows:

a. Cook failed to provide the warning or instruction and/or an adequate warning or instruction which a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that its Cook Filters would cause harm;

b. Cook manufactured and/or sold their Cook Filters and said filters did not conform to representations made by the Cook Defendants when they left their control;

c. Cook manufactured and/or sold their Cook Filters which were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, and the foreseeable risks associated with the Cook Filters' design or formulation exceeded the benefits associated with that design. These defects existed at the time the products left the Cook Defendants' control; and

d. Cook manufactured and/or sold their Cook Filters when they deviated in a material way from the design specifications, formulas or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards, and these defects existed at the time the products left the Cook Defendants' control.

100. The Cook Defendants' marketing of their Cook Filters was false and/or misleading.

101. Plaintiff, through her attending physicians, relied on these representations in determining which IVC filter to use for implantation in the Plaintiff.

102. Cooks' filters were unfit and unsafe for use by users as they posed an unreasonable and extreme risk of injury to persons using said products, such as the Plaintiff, and accordingly the Cook Defendants breached their expressed warranties and the implied warranties associated with the product.

103. The foregoing warranty breaches were a substantial factor in causing Plaintiff's injuries and damages as alleged.

104. As a direct and proximate result of the Cook Filters' defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiffs has lost her ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiffs has lost earnings and will continue to lose earnings into the future and has medical bills both past and future related to care because of the Cook Filters' defects.

105. By reason of the foregoing, Defendants are liable to the Plaintiffs for damages as a result of its breaches of implied warranty.

106. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and other such other and further relief as this Court deems just and proper.

COUNT VII – PUNITIVE DAMAGES

107. Plaintiffs repeat and reiterate the allegations previously set forth herein.

108. At all times material hereto, the Cook Defendants knew or should have known their Cook Filters were inherently dangerous with respect to the risk of tilt, fracture, migration and/or perforation.

109. At all times material hereto, the Cook Defendants attempted to misrepresent and did knowingly misrepresent facts concerning the safety of their Cook Filters.

110. The Cook Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff's physicians, concerning the safety of their Cook Filters. The Cook Defendants' conduct was willful, wanton, and undertaken with a conscious indifference to the consequences that consumers of their product faced, including Plaintiff.

111. At all times material hereto, Cook knew and recklessly disregarded the fact that their Cook IVC Filters have an unreasonably high rate of tilt, fracture, migration and/or perforation.

112. Notwithstanding the foregoing, the Cook Defendants continued to market their Cook Filters aggressively to consumers, including the Plaintiff, without disclosing the aforesaid

side effects.

113. The Cook Defendants knew of their Cook Filters' lack of warnings regarding the risk of fracture, migration, and/or perforation, but intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell their Filters without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious disregard of the foreseeable harm caused by Cook Filters.

114. The Cook Defendants' intentional and/or reckless failure to disclose information deprived the Plaintiff's physicians of necessary information to enable them to weigh the true risks of using Cook Filters against their benefits.

115. As a direct and proximate result of the Cook Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the safety and rights of consumers including the Plaintiff, the Plaintiff has suffered and will continue to suffer severe and permanent physical and emotional injuries, as described with particularity, above. Plaintiff has endured and will continue to endure pain, suffering, and loss of enjoyment of life; and has suffered and will continue to suffer economic loss, including incurring significant expenses for medical care and treatment and lost wages.

116. The Cook Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the safety and rights of consumers including the Plaintiff, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Cook Defendants and deter them from similar conduct in the future.

117. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and

seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and other such other and further relief as this Court deems just and proper.

TOLLING OF THE LIMITATIONS PERIOD

118. The Cook Defendants, through their affirmative misrepresentations and omissions, actively concealed from the Plaintiff and Plaintiff's healthcare providers the true and significant risks associated with Cook Filters.

119. As a result of the Cook Defendants' actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the result of Defendants' acts, omissions, and misrepresentations.

120. Accordingly, no limitations period ought to accrue until such time as Plaintiff knew or reasonably should have known of some causal connection between Plaintiff being implanted with a Cook Filter and the harm Plaintiff suffered as a result.

121. Additionally, the accrual and running of any applicable statute of limitations have been tolled by reason of the Cook Defendants' fraudulent concealment.

122. Additionally, the Cook Defendants are equitably estopped from asserting any limitations defense by virtue of their fraudulent concealment and other misconduct as described.

123. Additionally, the limitations period ought to be tolled under principles of equitable tolling.

PRAYER FOR RELIEF

124. WHEREFORE, Plaintiff demands judgment against the Cook Defendants as follows:

a. Compensatory damages, including without limitation past and future medical expenses; past and future pain and suffering; past and future emotional distress; past and future loss of enjoyment of life; past and future lost wages and loss of earning capacity; and consequential damages;

b. Punitive damages in an amount sufficient to punish Defendants and set an example;

c. Disgorgement of profits;

d. Restitution;

e. Costs and fees of this action, including reasonable attorney's fees;

f. Prejudgment interest and all other interest recoverable; and

g. Such other additional and future relief as Plaintiff may be entitled to in law or in equity according to the claims pled herein.

DEMAND FOR JURY TRIAL

Plaintiff respectfully requests trial by jury in the above case as to all issues.

Respectfully Submitted,

O'Leary, Shelton, Corrigan, Peterson, Dalton, & Quillin, LLC

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